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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,368	06/28/2001	David M. Allen	P1067	2222

7590

07/16/2002

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EXAMINER
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DEWITTY, ROBERT M

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/896,368

Applicant(s)

ALLEN, DAVID M.

Examiner

Robert M DeWitty

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 May 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 5-10 and 12-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-10, 12-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-3, 5-10, 12-23 are pending in the instant application. Acknowledgment is made of Applicant's amendment and response filed 5/22/02.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1, 5, 10, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has deleted the phrase "antimicrobial compound" in claims 1 and 10, but has not amended or deleted the phrase in all circumstances (see claim 1, line 7; claim 5, line 3, etc.). Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-3, 5-10, 12-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crandall (U.S. Pat. No. 5,560,910), further in view of Dawson (U.S. Pat. No. 6,239,113).

Crandall relates to compositions and methods for topically treating inflammation.

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Crandall's goals are to provide a method of administering an anti-inflammatory macromolecule that provides a more effective means of treating inflammation (in comparison with parenteral or oral treatment). The invention is useful for treating inflammatory conditions caused by infections due to microorganisms (col. 2, lines 2-13).

At example 1, the use of Pluronic Gel and Lecithin organogel in the composition are taught. Crandall does not teach using the macrolides azithromycin, erythromycin, or roxithromycin.

Dawson teaches the topical application of an azalide antibiotic such as azithromycin to the eye for the treatment of ocular infections (Abstract). Dawson teaches that infections of the eyelids, conjunctiva, cornea and other ocular tissues can arise. The prior art teaches that ocular infections are treated by local injection, systemic administration, or topical application. However, local injection and systemic administration have the risk of developing side effects or resistant strains of bacteria (col. 1, lines 29-35). Topical applications must be capable of a sufficient penetration rate to impart an effective dose (which may include penetration of the conjunctiva and the cornea). To address these issues, Dawson has discovered that azalide antibiotics are suitable for topical administration to the eye, a suitable antibiotic being azithromycin. Column 6, lines 15-48 teach the antibiotic used in combination with other medicaments.

Motivation to one with ordinary skill in the art to use a formula such as Crandall for carrying an antibiotic such as azithromycin for topical application would have arisen because such a formulation would have allowed sufficient delivery of the antibiotic to the eyelids. Further motivation to combine the two inventions would have arisen because

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Crandall invention provides effective delivery as compared with parenteral or oral, and it is preferable to deliver Dawson's invention topically to avoid side effects and resistant strains (both evident in local injection and systemic administration).

***Response to Arguments***


2. In light of Applicant's amendments and arguments with respect to claims 1-23, the previous rejections have been withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD  
July 12, 2002

  
**ALLEN J. ROBINSON**  
**PRIMARY EXAMINER**